**CAS MEDICAL SYSTEMS, INC.**

# *Ami® / Ami® Plus*

## Infant Apnea Monitor

# Bench Test Procedure

using the 8310 / 9310 Simulator

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TECHNOLOGY APPLIED TO MEDICINE

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# TABLE OF CONTENTS:

**I. Scope ..... 3**
**II. Maintenance Intervals ..... 3**
**III. Equipment Required ..... 3**
**IV. Initial Setup ..... 4**
**V. Equipment Setup ..... 4**

**1. Simulator Setup ..... 4**
**2. Ami Monitor Setup ..... 5**

**VI. Bench Test**

**1. Functional Test ..... 6**
**1.1 Human Alarm Test 1 ..... 6**
**1.2 Human Alarm Test 2 ..... 7**
**1.3 ECG Response Test ..... 8**
**1.4 Inverted Polarity Test ..... 9**
**1.5 Heart Beat = Respiration Test ..... 10**
**1.6 Lead Alarm Test ..... 10**
**1.7 Respiration Response Test ..... 11**
**1.8 Improper Shutoff Test ..... 12**
**1.9 Remote Alarm Test (Optional) ..... 12**
**1.10 Download Verification (Optional) ..... 12**

**VII. Test Data Sheet ..... 14**

**VIII. Acknowledgement Sign-Off Sheet..... 20**

# I. Scope

The purpose of this procedure is to provide a means by which a qualified person can perform a Bench Test to an Ami or Ami Plus monitor.

# II. Maintenance Intervals

CAS Medical Systems, Inc. recommends the following Maintenance Intervals for the Ami or Ami Plus monitor.

- Preventative Maintenance – In-Between Patients
- Bench Testing – Once every year
- Battery Replacement – Every (2) two years

# III. Equipment Required

To perform this procedure, you will need the following:

- Ami or Ami Plus monitor (hereafter referred to as Ami)
- Aequitron Model 8310 / CAS Model 9310 Simulator with updated software (see note) (p/n 01-05-0157)
- AC Power Cords (1 ea. for Ami and Simulator) (p/n 01-05-0139)
- Patient Cable (p/n 01-05-0004)
- Lead Wires (p/n 01-05-0005)
- 9712 Remote Alarm (p/n 01-05-0281) (Optional)
- Ami RG Software (p/n 01-05-0176) (Optional)
- Direct Download Cable (p/n 01-05-0283) (Optional)
- Stopwatch or equivalent
- Ami and Ami Plus Clinician's Manual (reference material) (p/n 21-02-0116)
- Ami Report Generator (RG) Software Manual (reference material) (p/n 01-05-0150)
- Model 9310 User's Manual (reference material) (p/n 21-02-0142)

**Note:** <u>8310 / 9310 Simulator</u>

This procedure requires the use of a Model 8310 / 9310 Simulator with updated software. The software has been updated with parameters specifically for testing the Lead Alarm and Respiration Response of the Ami monitor. The parameter selections added are; 1800 OHMS to the Electrode Impedance menu and 150 B/M to the Respiration Rate menu. Should your simulator not contain these selections, contact CAS Customer Service and obtain a Return Goods Authorization (RGA) number to have your simulator updated.

<u>Data Sheet Requirement</u>

This procedure uses a Data Sheet as the record for verifying monitor performance. Once the procedure is completed, CAS recommends the Data Sheet be kept with the respective monitor's Device History Record should verification of monitor performance be questioned.

# IV. Initial Setup

A. Connect the Ami power cord to the power receptacle on the rear panel of the monitor. Plug the other end of the power cord into a properly grounded A.C. outlet. Verify the green CHARGING visual indicator on the monitor is lit.

B. Connect the Simulator power cord to the power receptacle on the rear panel of the simulator. Plug the other end of the power cord into a properly grounded A.C. outlet.

C. Connect the Patient lead wires to the Patient Cable (white to RA; black to LA). Plug the male end of the lead wires into the Simulator (white to RA jack; black to LA jack).

D. Connect the Patient Cable to the PATIENT CABLE input receptacle located on the front panel of the monitor.

# V. Equipment Setup

## 1. Simulator Setup

A. Turn the Simulator ON by depressing the POWER ON/OFF switch located on the rear panel.

B. Once the Simulator has completed its power-on sequence, verify the following power-on factory default settings.

   a. ECG RATE = **165 BPM**
   b. ECG AMPLITUDE = **1.0 MV**
   c. RESPIRATION RATE = **30 B/M** (BrPM)
   d. RESPIRATION IMPEDANCE CHANGE = **1.0 OHMS**
   e. ELECTRODE IMPEDANCE = **500 OHMS**

NOTE: These power-on factory default settings are common to both the Model 8310 and 9310 Simulators. Contact CAS Technical Support should you have any questions or concerns.

## 2. AMI Monitor Setup

A. Power up the Ami monitor in the Setup mode.
To get into Setup Mode – On the bottom of the Ami apnea monitor, press the **UP Arrow** and the **ENTER** buttons and hold them. At the same time, press the **POWER** button on the front of the monitor, release the **POWER** button after the alarm, then release the **UP Arrow** and **ENTER** buttons. While in the Setup Mode, use the **UP** and **DOWN** Arrow keys to select a setting. Use the **ENTER** key to lock in the setting and move to the next selection. Use the **MODE** key to finish and move to the next screen. Refer to the **Setting Parameters** section in the Clinician's Manual for assistance.

B. At NEW PATIENT, select **YES** by pressing the **DOWN Arrow** button.
C. At ARE YOU SURE?, select **YES** by pressing the **ENTER** button. Verify, the monitor displays CLEARING MEMORY.
D. At PATIENT NAME, enter your initials. (Use the **UP** and **DOWN Arrows** to change the letter, after each letter press **ENTER**), when completed press **MODE**.
E. At PATIENT NUMBER, enter **1234**. (Use the **UP** and **DOWN Arrows** to change the number, after each number press **ENTER**), when completed press **MODE**.
F. Set BRADYCARDIA OPTION to **3 BEAT, 6 SECOND MAX**. Press **MODE**.
G. Set AUX. PORT 1 to **O2 SAT**. Press **MODE**.
H. Set OXIMETER CHOICE to **NPB-290/295/395**. Press **MODE**.
I. Set AUX. PORT 2 to **O2 PR**. Press **MODE**.
J. Set AUX. PORT 3 to **AIR FLOW**. Press **MODE**.
K. Set PRIORITY/FIFO/CONT to **FIFO**. Press **MODE**.
L. Set FIXED/FULL LENGTH to **FIXED 2 MINUTE**. Press **MODE**.
M. Set APNEA MONITOR ALARM LIMIT to **10 SEC**. Press **ENTER**.
N. Set HEART FAST MONITOR ALARM LIMIT to **250 BPM**. Press **ENTER**.
O. Set the HEART SLOW MONITOR ALARM LIMIT to **130 BPM**. Press **ENTER** followed by **MODE**.
P. Set the APNEA EVENT LOG LIMIT to **10 SEC**. Press **ENTER**.
Q. Set the HEART FAST EVENT LOG LIMIT to **250 BPM**. Press **ENTER**.
R. Set the HEART SLOW EVENT LOG LIMIT to **130 BPM**. Press **ENTER**.
S. Set the O2 SAT EVENT LOG LIMIT to **85%**. Press **ENTER** followed by **MODE**.
T. Scroll past AUX. PORT 1, 2, and 3 test screens (no selections are available). Press **MODE (4) times**.
U. Set TIME/DATE to current date and time. (Use the **UP** and **DOWN Arrows** and the **ENTER** buttons to make changes), when completed press **MODE**.
V. At SETUP COMPLETE?, select **YES**, by pressing the **ENTER** button.
W. At ARE YOU SURE?, select **YES** by pressing the **DOWN Arrow** button.

**NOTE:** Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

# VI. Bench Test

## 1. Functional Test

### 1.1 Human Alarm Test 1

A. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.

B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

C. Set the simulator ECG RATE to **265 BPM** by pressing the ECG RATE button then the Arrow UP button followed by pressing the ENTER button. Verify, the monitor HEART FAST visual indicator and audible alarm activate.

D. Set the simulator ECG RATE to **240 BPM** by pressing the ECG RATE button then the Arrow DOWN button followed by pressing the ENTER button. Verify, the monitor audible alarm silences and the HEART FAST visual indicator remains on.

E. Press the RESET button on the monitor. Verify, the HEART FAST visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

F. Set the simulator ECG RATE to **115 BPM** by pressing the ECG RATE button then the Arrow DOWN button followed by pressing the ENTER button. Verify, the monitor HEART SLOW visual indicator and audible alarm activates.

G. Set the simulator ECG RATE to **140 BPM** by pressing the ECG RATE button then the Arrow UP button followed by pressing the ENTER button. Verify, the monitor audible alarm silences and the HEART SLOW visual indicator remains on.

H. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

I. Set the simulator RESPIRATION RATE to **APNEA=INF SEC**. (Press RESPIRATION RATE button, hold the Arrow DOWN button until the LCD displays 00 and press ENTER. Hold the Arrow UP button until the LCD displays APNEA = INF SEC. Press ENTER to begin the apnea event).

    1. Begin timing for apnea with the last Respiration pulse. Stop timing when the apnea visual and audio alarm activates. Verify, the time is 10 +/- 1.0 seconds.

J. Press the RESPIRATION RATE button on the simulator. Verify, the monitor audible alarm silences and the APNEA visual indicator remains on.

K. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

L. Turn the Ami monitor OFF.

To turn OFF the Ami Apnea Monitor – Press and hold the **RESET** button, then press the **POWER** button at the same time. Release the **POWER** button (while still pressing the **RESET** button). Then release the **RESET** button. Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

Proceed to Human Alarm Test 2.

### 1.2 Human Alarm Test 2

**Note**: Do not choose New Patient when selecting new Human Alarm settings.

A. Power up the Ami monitor in Setup mode and select the following settings on the monitor:
   a. Set APNEA to **30 SEC**.
   b. Set HEART FAST to **125 BPM**.
   c. Set HEART SLOW to **40 BPM**.
   d. Default through to SETUP COMPLETE?, ARE YOU SURE? Select **YES**.

B. Set the simulator to the following settings:
   a. Set the ECG RATE to **115 BPM**.
   b. Set the RESPIRATION RATE to **30 BrPM**.

C. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.

D. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

E. Set the ECG RATE to **140 BPM**. Verify, the monitor HEART FAST visual indicator and audible alarm activates.

F. Set the ECG RATE to **115 BPM**. Verify, the monitor audible alarm silences and the HEART FAST visual indicator remains on.

G. Press the RESET button on the monitor. Verify, the HEART FAST visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

H. Set the ECG RATE to **35 BPM**. Verify, the monitor HEART SLOW visual indicator and audible alarm activates.

I. Set the ECG RATE to **45 BPM**. Verify, the monitor audible alarm silences and the HEART SLOW visual indicator remains on.

J. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

K. Set the simulator RESPIRATION RATE to **APNEA=INF SEC**. Press ENTER to begin the apnea event.
   1. Begin timing for apnea with the last Respiration pulse. Stop timing when the apnea visual and audio alarm activates. Verify, the time is 30 +/- 1.0 seconds.

L Press the RESPIRATION RATE button on the simulator. Verify, the monitor audible alarm silences and the APNEA visual indicator remains on.

M. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears and the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator.

N. Turn the Ami monitor OFF. Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

Proceed to ECG Response Test.

### 1.3 ECG Response Test

**Note**: Do not choose New Patient when selecting new Human Alarm settings.

A. Power up the monitor in Setup mode and select the following settings on the monitor.
   a. Set APNEA to **15 SEC**.
   b. Set HEART FAST to **OFF**.
   c. Set HEART SLOW to **40 BPM**.
   d. Default to SETUP COMPLETE?, ARE YOU SURE? Select **YES**.

B. Set the simulator to the following settings:
   a. Set the ECG RATE to **165 BPM**.
   b. Set the RESPIRATION RATE to **20 BrPM**.

C. Press the POWER button on the monitor. Once the monitor has completed its power up sequence (approximately 45 seconds), verify Good Connection/Best Signal or Best Connection/Best Signal on the monitor LCD.

D. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

E. Set the ECG RATE to **45 BPM** and the ECG AMPLITUDE (AMPL) to **0.2 mV**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

F. Set the ECG AMPLITUDE to **0.1 mV**. Verify, 1) the HEART BEAT indicator is no longer flashing 2) the RESPIRATION indicator continues to flash at the rate set on the simulator and 3) the monitor HEART SLOW visual indicator and audible alarm activate.

G. Set the ECG AMPLITUDE to **1.0 mV**. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the HEART SLOW visual indicator remains on.

H. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

I. Set the ECG RATE to **265 BPM** and the ECG AMPLITUDE to **0.2 mV**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

J. Set the ECG AMPLITUDE to **0.1 mV**. Verify, 1) the HEART BEAT indicator is no longer flashing 2) the RESPIRATION indicator continues to flash at the rate set on the simulator and 3) the monitor HEART SLOW visual indicator and audible alarm activate.

K. Set the ECG AMPLITUDE to **5.0 mV**. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the HEART SLOW visual indicator remains on.

L. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

M. Set the ECG RATE to **45 BPM**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

N. Set the ECG RATE to **165 BPM** and the ECG AMPLITUDE to **1.0 mV**.

Proceed to the Inverted Polarity Test.

### 1.4 Inverted Polarity Test

A. Disconnect the white and black lead wires from the simulator. Verify, the LOOSE LEAD visual indicator and audible alarm activate.

B. Connect the white lead to the LA jack and the black lead to the RA jack on the simulator. Verify, the audible alarm silences and the LOOSE LEAD visual indicator remains on. (leave the connections reversed).

C. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.

D. Set the ECG RATE to **45 BPM** and the ECG AMPLITUDE (AMPL) to **0.2 mV**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

E. Set the ECG AMPLITUDE to **0.1 mV**. Verify, 1) the HEART BEAT indicator is no longer flashing 2) the RESPIRATION indicator continues to flash at the rate set on the simulator and 3) the monitor HEART SLOW visual indicator and audible alarm activate.

F. Set the ECG AMPLITUDE to **1.0 mV**. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the HEART SLOW visual indicator remains on.

G. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

H. Set the ECG RATE to **265 BPM** and the ECG AMPLITUDE to **0.2 mV**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

I. Set the ECG AMPLITUDE to **0.1 mV**. Verify, 1) the HEART BEAT indicator is no longer flashing 2) the RESPIRATION indicator continues to flash at the rate set on the simulator and 3) the monitor HEART SLOW visual indicator and audible alarm activate.

J. Set the ECG AMPLITUDE to **5.0 mV**. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the HEART SLOW visual indicator remains on.

K. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

L. Set the ECG RATE to **45 BPM**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

M. Set the ECG RATE to **165 BPM** and the ECG AMPLITUDE to **1.0 mV**.

N. Disconnect the lead wires from the simulator. Re-connect the white and black lead wires onto their appropriate jacks on the simulator. Verify, the LOOSE LEAD visual indicator and audible alarm activate until the Lead Wires are reconnected.

O. Once the lead wires have been re-connected, verify, the audible alarm silences and the LOOSE LEAD visual indicator remains on.

P. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.

Proceed to the Heart Beat = Respiration Test.

### 1.5 Heart Beat = Respiration Test

A. Set the simulator to the following settings:
   a. Set the ECG RATE to **95 BPM**.
   b. Set the ECG AMPLITUDE to **1.0 mV**.
   c. Set the RESPIRATION RATE to **50 BrPM**.
   d. Set the RESPIRATION IMPEDANCE CHANGE to **1.0 OHMS**.

B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

C. Set the simulator to the following settings:
   a. Set the ECG RATE to **75 BPM**.
   b. Set the RESPIRATION RATE to **75 BrPM**.

D. Verify, 1) the HEART BEAT indicator continues to flash at the rate set on the simulator 2) the RESPIRATION indicator is no longer flashing and 3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds.

E. Set the RESPIRATION RATE to **50 BrPM**. Verify, 1) the monitor audible alarm silences 2) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator and 3) the APNEA visual indicator remains on.

F. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.

Proceed to the Lead Alarm Test.

### 1.6 Lead Alarm Test

A. Set the simulator ELECTRODE IMPEDANCE to **1800 OHMS**. Verify, the monitor LOOSE LEAD visual indicator and audible alarm activate.

B. Set the simulator ELECTRODE IMPEDANCE to **1500 OHMS**. Verify, the monitor audible alarm silences and the LOOSE LEAD visual indicator remains on.

C. Press the RESET button on the monitor. Verify, the LOOSE LEAD visual indicator clears.

D. Set the simulator ELECTRODE IMPEDANCE to **500 OHMS**.

Proceed to the Respiration Response Test.

### 1.7 Respiration Response Test

A. Set the simulator to the following settings:

   a. Set the ECG RATE to **215 BPM**.

   b. Set the RESPIRATION RATE to **30 BrPM**.

B. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

C. Set the RESPIRATION IMPEDANCE to **0.2 OHMS**. Verify the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator with no other Human Alarm visual indicators or audible alarms active.

D. Set the RESPIRATION IMPEANCE to **0.1 OHMS**. Verify, 1) the RESPIRATION indicator is no longer flashing 2) the HEART BEAT indicator continues to flash at the rate set on the simulator and 3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds.

E. Set the RESPIRATION IMPEDANCE to **0.3 OHMS**. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator 2) the monitor audible alarm silences and 3) the APNEA visual indicator remains on.

F. Press the RESET button on the monitor. Verify, the APNEA visual indicator clears.

G. Set the RESPIRATION RATE to **10 BrPM** and the RESPIRATION IMPEDANCE to **0.5 OHMS**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

H. Set the RESPIRATION RATE to **150 BrPM** and the RESPIRATION IMPEDANCE to **0.5 OHMS**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

I. Set the RESPIRATION RATE to **150 BrPM** and the RESPIRATION IMPEDANCE to **5.0 OHMS**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

J. Set the RESPIRATION RATE to **10 BrPM** and the RESPIRATION IMPEDANCE to **5.0 OHMS**. Verify, the HEART BEAT and RESPIRATION indicators continue to flash at the rate set on the simulator and all Human Alarm visual indicators are OFF.

K. Set the simulator to the following settings:

   a. Set the ECG RATE to **165 BPM**.

   b. Set the RESPIRATION RATE to **30 BrPM**.

   c. Set the RESPIRATION IMPEDANCE to **1.0 OHMS**.

Proceed to Improper Shutoff Test (Sibling Protection Alarm).

### 1.8 Improper Shutoff Test (Sibling Protection Alarm)

A. Press the POWER button on the monitor. Verify, 1) the HEART BEAT and RESPIRATION indicators are flashing at the rate set on the simulator and 2) an audible alarm is active with NO Human visual alarm indicators lit.

B. Press the POWER button on the monitor. Verify, 1) the audible alarm silences and 2) the monitor continues to count at the rate set on the simulator.

Proceed to Remote Alarm Test.

### 1.9 Remote Alarm Test (Optional)

A. Obtain the Remote Alarm and cable used with the monitor and connect them to the Remote Alarm jack, located on the rear panel of the monitor.

B. Apply power to the Remote Alarm by pressing the "ON" key switch, located on the front panel. Verify, the green POWER indicator is flashing with no visual or audible alarms.

C. Set the ECG AMPLITUDE to **0 mV** and press the RESET button on the monitor. Verify, 1) Good Connection/Poor Signal or Best Connection/Poor Signal on the monitor LCD 2) a HEART SLOW visual and audible alarm on the monitor and 3) a red flashing ALARM visual indicator and audible alarm on the Remote Alarm.

D. Set the ECG AMPLITUDE to **1.0 mV**. Verify on the Remote Alarm, the audible alarm silences and the ALARM visual indicator is no longer flashing.

E. Turn the Remote Alarm OFF by pressing both the * and POWER key switches at the same time. Verify, the POWER indicator is no longer flashing.

F. Press the RESET button on the monitor. Verify, the HEART SLOW visual indicator clears.

G. Turn the Ami monitor OFF. Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

H. Disconnect the Remote Alarm from the monitor.

Proceed to Download Verification.

### 1.10Download Verification (Optional)

**NOTE:** Refer to the RG Software Manual, Section 5, Connecting to the Monitor for assistance.

A. Connect the monitor to the computer using the Direct Download Cable.

B. Launch the RG Software program and perform a Direct Download of the data stored in the monitor.

C. Review the Monitor Logs Report and verify, 1) correct date and time information 2) correct New Patient Name and Number 3) correct Apnea, Heart Slow and Heart Fast Alarm Limit changes and 4) monitor Power Up / Down and Setup Event Types.

D. Review the Patient Logs Report and verify, 1) correct date and time information 2) correct Apnea, Heart Slow and Heart Fast Event Type and Durations.

E. Print a copy of both the Monitor Logs and Patient Logs reports. Attach them to the back of the completed Data Sheet.

F. Turn the Ami monitor OFF. Wait for the monitor to complete its power down sequence (approximately 25 – 35 seconds), which will be distinguished by an audio sound.

Turn the simulator OFF. Disconnect the monitor from the simulator and computer as needed.

This concludes the Ami / Ami Plus Bench Test Procedure.

Should you have any questions, do not hesitate to contact CAS Technical Support at 203-488-6056 / 800-581-7806 (US only) (phone), 203-488-9438 (fax) or www.techsrv@casmed.com (email).

Date: _____

Tested By: _____

# VII. Test Data Sheet

## Ami /Ami Plus Infant Apnea Monitor

using the 8310 / 9310 Simulator

Home Care Dealer / Hospital:

_____

Address: _____

City: _____

State: _____ Zip: _____

Ami Type: (select one) Ami ( ) ; Ami Plus ( )

Ami Serial Number: _____

Simulator Type / Serial Number: _____

Simulator Calibration Date: _____

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IV. Initial Setup

| | | |
|---|---|---|
| A. | Connect the power cord to the Ami monitor. Verify, green CHARGING indicator is lit. | Pass ( ) Fail ( ) |
| B. | Connect the power cord to the simulator. | Completed ( ) |
| C. | Connect the Patient Leads to the Patient Cable and Simulator. | Completed ( ) |
| D. | Connect the Patient Cable to the Patient Cable input on the Ami monitor. | Completed ( ) |

V. Equipment Setup

1. Simulator Setup

| | | |
|---|---|---|
| A. | Turn the simulator ON. | Completed ( ) |
| B. | Verify the following power on default settings: | |
| a. | ECG RATE = 165 BPM | Pass ( ) Fail ( ) |
| b. | ECG AMPLITUDE = 1.0 MV | Pass ( ) Fail ( ) |
| c. | RESPIRATION RATE = 30 B/M | Pass ( ) Fail ( ) |
| d. | RESPIRATION IMPEDANCE CHANGE = 1.0 OHMS | Pass ( ) Fail ( ) |
| e. | ELECTRODE IMPEDANCE = 500 OHMS | Pass ( ) Fail ( ) |

2. Ami Monitor Setup

| | | |
|---|---|---|
| A. | Power up the monitor in the Setup Mode. | Completed ( ) |
| B. | At NEW PATIENT, select YES. | Completed ( ) |
| C. | At ARE YOU SURE?, select YES. Verify, monitor displays CLEARING MEMORY. | Pass ( ) Fail ( ) |
| D. | At PATIENT NAME, enter your initials. | Completed ( ) |
| E. | At PATIENT NUMBER, enter 1234. | Completed ( ) |
| F. | Set BRADYCARDIA OPTION to 3 BEAT, 6 SECOND MAX. | Completed ( ) |
| G. | Set AUX. PORT 1 to O2 SAT. | Completed ( ) |
| H. | Set OXIMETER CHOICE to NPB-290/295/395. | Completed ( ) |
| I. | Set AUX. PORT 2 to O2 PR. | Completed ( ) |
| J. | Set AUX. PORT 3 to AIR FLOW. | Completed ( ) |
| K. | Set PRIORITY/FIFO/CONTINUE to FIFO. | Completed ( ) |
| L. | Set FIXED/FULL LENGTH to FIXED 2 MINUTE. | Completed ( ) |
| M. | Set APNEA MONITOR ALARM LIMIT to 10 SEC. | Completed ( ) |
| N. | Set HEART FAST MONITOR ALARM LIMIT to 250 BPM. | Completed ( ) |
| O. | Set HEART SLOW MONITOR ALARM LIMIT to 130 BPM. | Completed ( ) |

P. Set APNEA EVENT LOG LIMIT to 10 SEC. Completed ( )
Q. Set HEART FAST EVENT LOG LIMIT to 250 BPM. Completed ( )
R. Set HEART SLOW EVENT LOG LIMIT to 130 BPM. Completed ( )
S. Set O2 SAT EVENT LOG LIMIT to 85%. Completed ( )
T. Scroll past AUX. PORT 1, 2 and 3 test screens. Completed ( )
U. Set TIME and DATE information. Completed ( )
V. At SETUP COMPLETE?, select YES. Completed ( )
W. At ARE YOU SURE?, select YES. Verify, proper monitor power down. Pass ( ) Fail ( )

## VI. Bench Test

### 1. Functional Test

#### 1.1 Human Alarm - Test 1

A. Press the POWER button on the monitor.
Verify, Good Connection/Best Signal or Best Connection/Best Signal on LCD. Pass ( ) Fail ( )
B. Verify, monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )
C. Set the simulator ECG RATE to 265. Verify, HEART FAST visual and audible alarms. Pass ( ) Fail ( )
D. Set the simulator ECG RATE to 240. Verify, audible stops and HEART FAST visual remains on. Pass ( ) Fail ( )
E. Press RESET. Verify, HEART FAST visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )
F. Set the simulator ECG RATE to 115. Verify, HEART SLOW visual and audible alarms. Pass ( ) Fail ( )
G. Set the simulator ECG RATE to 140. Verify, audible stops and HEART SLOW visual remains on. Pass ( ) Fail ( )
H. Press RESET. Verify, HEART SLOW visual clear and monitor counts rates set on simulator. Pass ( ) Fail ( )
I. Set the simulator RESPIRATION RATE to APNEA = INF SEC. Press ENTER.
1. Verify, the time to be 10 +/- 1.0 seconds. Pass ( ) Fail ( )
J. Press the RESPIRATION RATE on the simulator. Verify, audible stops and APNEA visual remains on. Pass ( ) Fail ( )
K. Press RESET on monitor. Verify, APNEA visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )
L. Turn the monitor OFF. Verify, proper monitor power down. Pass ( ) Fail ( )

#### 1.2 Human Alarm - Test 2

NOTE: Do not choose NEW PATIENT when selecting new Human Alarm settings.

A. Power up the monitor in the Setup Mode and select the following settings on the monitor.
a. Set APNEA to 30. Completed ( )
b. Set HEART FAST to 125. Completed ( )
c. Set HEART SLOW to 40. Completed ( )
d. Default through to SETUP COMPLETE?, ARE YOU SURE? and select YES. Completed ( )
B. Set the simulator to the following settings:
a. Set the ECG RATE to 115. Completed ( )
b. Set the RESPIRATION RATE to 30. Completed ( )
C. Press the POWER button on the monitor.
Verify, Good Connection/Best Signal or Best Connection/Best Signal on LCD. Pass ( ) Fail ( )
D. Verify, monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )
E. Set the simulator ECG RATE to 140. Verify, HEART FAST visual and audible alarms. Pass ( ) Fail ( )
F. Set the simulator ECG RATE to 115. Verify, audible stops and HEART FAST visual remains on. Pass ( ) Fail ( )
G. Press RESET. Verify, HEART FAST visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )
H. Set the simulator ECG RATE to 35. Verify, HEART SLOW visual and audible alarms. Pass ( ) Fail ( )
I. Set the simulator ECG RATE to 45. Verify, audible stops and HEART SLOW visual remains on. Pass ( ) Fail ( )
J. Press RESET. Verify, HEART SLOW visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )
K. Set the simulator RESPIRATION RATE to APNEA = INF SEC. Press ENTER.
1. Verify, the time to be 30 +/- 1.0 seconds. Pass ( ) Fail ( )

L. Press the RESPIRATION RATE on the simulator. Verify, audible stops and APNEA visual remains on. Pass ( ) Fail ( )

M. Press RESET. Verify, APNEA visual clears and monitor counts rates set on simulator. Pass ( ) Fail ( )

N. Turn the monitor OFF. Verify, proper monitor power down. Pass ( ) Fail ( )

1.3 ECG Response Test

NOTE: Do not choose NEW PATIENT when selecting new Human Alarm settings.

A Power up the monitor in the Setup Mode and select the following settings on the monitor.

a. Set APNEA to 15. Completed ( )

b. Set HEART FAST to OFF. Completed ( )

c. Set HEART SLOW to 40. Completed ( )

d. Default through to SETUP COMPLETE?, ARE YOU SURE? and select YES. Completed ( )

B. Set the simulator to the following settings:

a. Set the ECG RATE to 165. Completed ( )

b. Set the RESPIRATION RATE to 20. Completed ( )

C. Press the POWER button on the monitor. Verify, Good Connection/Best Signal or Best Connection/Best Signal on LCD. Pass ( ) Fail ( )

D. Verify, monitor counts rates set on simulator with no alarms. Pass ( ) Fail ( )

E. Set the ECG RATE to 45 and the ECG AMPL to 0.2. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

F. Set the ECG AMPLITUDE to 0.1. Verify,

1) the HEART BEAT is no longer flashing. Pass ( ) Fail ( )

2) the RESPIRATION indicator continues to flash at the rate set on simulator. Pass ( ) Fail ( )

3) HEART SLOW visual and audible alarms. Pass ( ) Fail ( )

G. Set the ECG AMPLITUDE to 1.0. Verify,

1) monitor counts rates set on simulator. Pass ( ) Fail ( )

2) audible alarm silences. Pass ( ) Fail ( )

3) HEART SLOW visual on. Pass ( ) Fail ( )

H. Press RESET. Verify, HEART SLOW visual clears. Pass ( ) Fail ( )

I. Set the ECG RATE to 265 and the ECG AMPL to 0.2. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

J. Set the ECG AMPLITUDE to 0.1. Verify,

1) the HEART BEAT is no longer flashing. Pass ( ) Fail ( )

2) the RESPIRATION indicator continues to flash at the rate set on simulator. Pass ( ) Fail ( )

3) HEART SLOW visual and audible alarms. Pass ( ) Fail ( )

K. Set the ECG AMPL to 5.0. Verify,

1) monitor counts rates set on simulator. Pass ( ) Fail ( )

2) audible alarm silences. Pass ( ) Fail ( )

3) HEART SLOW visual on. Pass ( ) Fail ( )

L. Press RESET. Verify, HEART SLOW visual clears. Pass ( ) Fail ( )

M. Set the ECG RATE to 45. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

N. Set the ECG RATE to 165 and the ECG AMPLITUDE to 1.0. Completed ( )

1.4 Inverted Polarity Test

A. Disconnect the Lead Wires from the simulator. Verify LOOSE LEAD visual and audible alarms. Pass ( ) Fail ( )

B. Connect the white lead to the LA jack and the black lead to the RA jack. Verify, the audible stops and the LOOSE LEAD visual remains on. Pass ( ) Fail ( )

C. Press RESET. Verify, LOOSE LEAD visual clears. Pass ( ) Fail ( )

D. Set the ECG RATE to 45 and the ECG AMPL to 0.2. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

E. Set the ECG AMPLITUDE to 0.1. Verify,
   1) the HEART BEAT is no longer flashing. Pass ( ) Fail ( )
   2) the RESPIRATION indicator continues to flash at the rate set on simulator. Pass ( ) Fail ( )
   3) HEART SLOW visual and audible alarms. Pass ( ) Fail ( )

F. Set the ECG AMPLITUDE to 1.0. Verify,
   1) monitor counts rates set on simulator. Pass ( ) Fail ( )
   2) audible alarm silences. Pass ( ) Fail ( )
   3) HEART SLOW visual on. Pass ( ) Fail ( )

G. Press RESET. Verify, HEART SLOW visual clears. Pass ( ) Fail ( )

H. Set the ECG RATE to 265 and the ECG AMPL to 0.2. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

I. Set the ECG AMPLITUDE to 0.1. Verify,
   1) the HEART BEAT is no longer flashing. Pass ( ) Fail ( )
   2) the RESPIRATION indicator continues to flash at the rate set on simulator. Pass ( ) Fail ( )
   3) HEART SLOW visual and audible alarms. Pass ( ) Fail ( )

J. Set the ECG AMPL to 5.0. Verify,
   1) monitor counts rates set on simulator. Pass ( ) Fail ( )
   2) audible alarm silences. Pass ( ) Fail ( )
   3) HEART SLOW visual on. Pass ( ) Fail ( )

K. Press RESET. Verify, HEART SLOW visual clears. Pass ( ) Fail ( )

L. Set the ECG RATE to 45. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )

M. Set the ECG RATE to 165 and the ECG AMPLITUDE to 1.0. Completed ( )

N. Disconnect the Lead Wires from the simulator. Re-connect the white and black lead wires onto their appropriate jacks on the simulator. Verify, LOOSE LEAD visual and audible alarms activate. Pass ( ) Fail ( )

O. Once the lead wires have been reconnected. Verify, the audible alarm silences and the LOOSE LEAD visual remains on. Pass ( ) Fail ( )

P. Press RESET. Verify, LOOSE LEAD visual clears. Pass ( ) Fail ( )

1.5 Heart Beat = Respiration Test

A. Set the simulator to the following settings:
   a. ECG RATE = 95. Completed ( )
   b. ECG AMPLITUDE = 1.0. Completed ( )
   c. RESPIRATION RATE = 50. Completed ( )
   d. RESPIRATION IMPEDANCE CHANGE = 1.0. Completed ( )

B. Verify, monitor counts rate set on simulator with no alarms. Pass ( ) Fail ( )

C. Set the ECG RATE and RESPIRATION RATE to 75. Completed ( )

D. Verify,
   1) the HEART BEAT indicator continues to flash at the rate set on the simulator. Pass ( ) Fail ( )
   2) the RESPIRATION indicator is no longer flashing. Pass ( ) Fail ( )
   3) the monitor audible alarm and APNEA visual indicator are activated after 15 seconds. Pass ( ) Fail ( )

E. Set the RESPIRATION RATE to 50. Verify,
   1) the monitor audible alarm silences. Pass ( ) Fail ( )
   2) the HEART BEAT and RESPIRATION indicators flash at the rates set on the simulator. Pass ( ) Fail ( )
   3) the APNEA visual indicator remains on. Pass ( ) Fail ( )

F. Press RESET. Verify, APNEA visual clears. Pass ( ) Fail ( )

1.6 Lead Alarm Test

A. Set the ELECTRODE IMPEDANCE to 1800. Verify, LOOSE LEAD visual and audible alarms. Pass ( ) Fail ( )
B. Set the ELECTRODE IMPEDANCE to 1500. Verify, the audible stops and the LOOSE LEAD visual remains on. Pass ( ) Fail ( )
C. Press RESET. Verify, LOOSE LEAD visual clears. Pass ( ) Fail ( )
D. Set the ELECTRODE IMPEDANCE to 500. Completed ( )

1.7 Respiration Response Test

A. Set the ECG RATE to 215 and the RESPIRATION RATE to 30. Completed ( )
B. Verify, monitor counts rates set on simulator with no alarms. Pass ( ) Fail ( )
C. Set the RESPIRATION IMPEDANCE to 0.2. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )
D. Set the RESPIRATION IMPEDANCE to 0.1. Verify,
   1) the RESPIRATION indicator is no longer flashing. Pass ( ) Fail ( )
   2) the HEART BEAT indicator continues to flash at the rate set on simulator. Pass ( ) Fail ( )
   3) the audible alarm and APNEA visual are active after 15 seconds. Pass ( ) Fail ( )
E. Set the RESPIRATION IMPEDANCE to 0.3. Verify,
   1) the HEART BEAT and RESPIRATION indicators are flashing at the rates set on the simulator. Pass ( ) Fail ( )
   2) the audible alarm silences. Pass ( ) Fail ( )
   3) the APNEA visual indicator remains on. Pass ( ) Fail ( )
F. Press RESET. Verify, APNEA visual clears. Pass ( ) Fail ( )
G. Set the RESPIRATION RATE to 10 and the RESPIRATION IMPEDANCE to 0.5. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )
H. Set the RESPIRATION RATE to 150 and the RESPIRATION IMPEDANCE to 0.5. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )
I. Set the RESPIRATION RATE to 150 and the RESPIRATION IMPEDANCE to 5.0. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )
J. Set the RESPIRATION RATE to 10 and the RESPIRATION IMPEDANCE to 5.0. Verify, monitor continues to count rates set on simulator with no alarms. Pass ( ) Fail ( )
K. Set the simulator to the following settings:
   a. ECG RATE = 165. Completed ( )
   b. RESPIRATION RATE = 30. Completed ( )
   c. RESPIRATION IMPEDANCE CHANGE = 1.0. Completed ( )

1.8 Improper Shutoff Test (Sibling Protection Alarm)

A. Press the POWER button on the monitor. Verify,
   1) the HEART BEAT and RESPIRATION indicators are flashing at the rates set on the simulator. Pass ( ) Fail ( )
   2) an audible alarm is active with no human visual alarm indicators lit. Pass ( ) Fail ( )
B. Press the POWER button on the monitor. Verify,
   1) the audible alarm silences. Pass ( ) Fail ( )
   2) the monitor continues to count at the rates set on the simulator. Pass ( ) Fail ( )

1.9 Remote Alarm Test

| | | |
|---|---|---|
| A. | Connect the Remote Alarm to the monitor. | Completed ( ) |
| B. | Press the ON key switch. Verify, POWER visual indicator flashing with no audible or visual alarm. | Pass ( ) Fail ( ) |
| C. | Set the ECG AMPLITUDE to 0. Press the RESET button on the monitor. Verify, | |
| | 1) Good Connection/Poor Signal or Best Connection/Poor Signal on the LCD. | Pass ( ) Fail ( ) |
| | 2) a HEART SLOW visual and audible alarm on the monitor. | Pass ( ) Fail ( ) |
| | 3) a red flashing ALARM visual indicator and an audible alarm on the Remote Alarm. | Pass ( ) Fail ( ) |
| D. | Set the ECG AMPLITUDE to 1.0. Verify on the Remote Alarm, the audible alarm silences and the ALARM visual indicator is no longer flashing. | Pass ( ) Fail ( ) |
| E. | Turn the Remote Alarm OFF. Verify, the POWER indicator is no longer flashing. | Pass ( ) Fail ( ) |
| F. | Press the RESET button on the monitor. Verify, the HEART SLOW visual clears. | Pass ( ) Fail ( ) |
| G. | Turn the monitor OFF. Verify, proper monitor power down. | Pass ( ) Fail ( ) |
| H. | Disconnect the Remote Alarm from the monitor. | Completed ( ) |

1.10 Download Verification

| | | |
|---|---|---|
| A. | Connect the monitor to the computer using the Direct Download Cable. | Completed ( ) |
| B. | Launch the RG program and perform a Direct Download of data stored in the monitor. | Completed ( ) |
| C. | Review the Monitor Logs Report and verify, | |
| | 1) correct date and time information. | Pass ( ) Fail ( ) |
| | 2) correct New Patient Name and Number. | Pass ( ) Fail ( ) |
| | 3) correct Apnea, Heart Slow and Heart Fast Alarm Limit changes. | Pass ( ) Fail ( ) |
| | 4) monitor Power Up / Down and Setup Event Types. | Pass ( ) Fail ( ) |
| D. | Review the Patient Logs Report and verify, | |
| | 1) correct date and time information. | Pass ( ) Fail ( ) |
| | 2) correct Apnea, Heart Slow and Heart Fast Event Type and Durations. | Pass ( ) Fail ( ) |
| E. | Print a copy of both reports. Attach them to the completed Data Sheet. | Completed ( ) |
| F. | Turn the Ami monitor OFF. Verify proper monitor power down. | Pass ( ) Fail ( ) |

If the monitor fails to pass any part of this procedure, please return a copy of this Data Sheet with the monitor when it is returned for service.

Comments: _____

_____

_____

_____

This concludes the Ami/Ami Plus Test Data Sheet.

# VIII. Certification Acknowledgement Sign-Off Sheet

Home Care Dealer / Hospital: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax Phone: _____

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By signing below, I have read and understood the Ami / Ami Plus Bench Test Procedure and agree to adhere to it using the equipment required to the best of my ability.

Print Name, as it would appear on the certificate of the individual being certified:

_____

Signature: _____ Date: _____

Email Address: _____

Would you like to be contacted concerning any product updates / improvements? Yes ( ) No ( )

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Once completed, keep a copy for your records and mail the original sign-off sheet to:

CAS Medical Systems, Inc.
44 E. Industrial Rd
Branford, CT 06405 USA

203-488-6056 / 800-227-4414 (US only)(phone)
203-488-9438 (fax)
www.casmed.com

ATTN: Anthony F. Cop
Product Support Manager
acop@casmed.com

This Sign-Off Sheet may be copied if additional individuals will be certified.